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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,091	08/15/2005	George B. Stefano	R1381-200US	6473
23550	7590	03/17/2010	EXAMINER	
HOFFMAN WARNICK LLC			WINSTON, RANDALL O	
75 STATE STREET			ART UNIT	
14TH FLOOR			PAPER NUMBER	
ALBANY, NY 12207			1655	
			NOTIFICATION DATE	DELIVERY MODE
			03/17/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOCommunications@hoffmanwarnick.com

Office Action Summary

Application No.

10/526,091

Applicant(s)

STEFANO ET AL.

Examiner

Randall Winston

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 1209

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2009 has been entered.

Claims 1-7 and 15-18 have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is rendered vague in indefinite because of the phrase "an effective amount of an extract of a plant" and "preparing an extract from said plant parts." It is unclear to Examiner of what type of extract is Applicant preparing? Is Applicant preparing either a water soluble extract and/or organic solvent extract and/or an alcohol extract to extract the plant part material of *Salix alba* to obtain an extract containing the claimed compounds therein to aid in stimulating nitric oxide production? Clarification is required.

Claim 15 step a recites the limitation of "the plant." There is insufficient antecedent basis for the limitation in the claim.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by or in the alternative, under 35 U.S.C. 103(a) as being obvious over (PDR for Herbal Medicines, First Edition, *Salix Species*, pages 1111-1112, copyrighted 1998) or (The Healing Herbs, The Ultimate Guide to the Curative Power of nature's Medicines, *White Willow*, pages 369-371, copyrighted 1991)

Applicant claims a pharmaceutical composition comprising a water extract of *Salix alba* (i.e. the bark and/or leave and/or flower) whereas the water soluble extract contains water soluble components and/or compounds having a claimed molecular weight therein.

PDR for Herbal Medicine reference as well as The Healing Herb reference each teach a pharmaceutical composition which appears to be the same as that instantly claimed since both the claimed invention and each of the reference compositions comprise a water extract of the bark (i.e. the bark is in powdered form) of the same *Salix alba* species. Therefore, when The PDR for Herbal Medicine reference or The Healing Herb's reference performs the same extraction process of extracting the bark of the same *Salix alba* species with the same solvent such as water as the claimed invention's extraction process, both extraction processes of the cited references and the claimed invention would both inherently contain water soluble components and/or compounds having the claimed molecular weight therein (see, e.g. PDR for Herbal Medicine entire abstract including pages 1111-1112, especially under preparation or The Healing Herb entire abstract including pages 369-371 especially page 371 under RX for White Willow). Therefore, reference is deemed to anticipate the claimed invention.

In the alternative, even if the claimed composition is not identical to the referenced composition in regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics

which they have been shown. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please note, the intended use of the above claimed composition (i.e. the functional effects and/or properties instantly claimed would be inherent to the prior art reference) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Applicant argument has been carefully considered but it is not deemed persuasive. Applicant argues that according to the declaration of 10/27/2009 submitted

with his response, Applicant's declaration from Dr. Stefano has specifically identified four of the compounds contained in the claimed composition whereas Applicant has also shown the compounds' additive and /or synergistic characteristics for "stimulating nitric oxide production." Examiner has not found Applicant argument persuasive because as Examiner stated above in his 35 USC 102/103 rejection that when The PDR for Herbal Medicine reference or The Healing Herb's reference performs the same extraction process of extracting the bark of the same *Salix alba* species with the same solvent such as water as the claimed invention's extraction process, both extraction processes of the cited references and the claimed invention would both inherently contain water soluble components and/or compounds having the claimed molecular weight therein. Furthermore, please note that the intended use of the above claimed composition (i.e. the functional effects and/or properties instantly claimed of stimulating nitric oxide production would be inherent to the prior art reference) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655